

REMARKS

After entry of the present Amendment, claims 1-7, 9-11, 13, 15, 16, 23, 27 and 28 are pending in the Application. Claims 8, 12 and 14 were cancelled and claims 1, 5, 7, 9, 11, 13, 15, 23 and 28 were amended. No new matter is introduced. Applicants submit that the specification supports the amended claims. In particular, "traditional snack" is defined at page 3, lines 8-12. Support for the recitation of "at least about 0.75 grams of beta glucan soluble fiber" can be found in the specification at least at pages 6, lines 15-16, and support for the recitation of "at least about 2% beta glucan" in the sheetable dough of claim 23 can be found in the specification at least at page 6, lines 30-31.

The pending claims stand variously rejected. Each rejection is respectfully traversed as discussed below. Applicants respectfully submit that the presently pending claims are in condition for allowance and earnestly solicit notification to that effect.

Resubmission of IDS filed May 10, 2002

The Office Action indicates that an IDS filed by Applicants on May 10, 2002, as well as the references cited therein, cannot be located. Upon the suggestion of Examiner Bahar, submitted herewith is a duplicate IDS and copies of the references cited. Applicants respectfully request consideration of these references.

Rejection under 35 U.S.C. § 103

Claims 1-16, 23 (in part) and 27-28 stand rejected under 35 U.S.C. § 103 as being obvious over Jandacek (U.S. Patent No. 4,005,195) in view of Akoh and an FDA announcement abstract. The rejection is respectfully traversed. As demonstrated below, a prima facie case of obviousness has not been established with respect to the present claims. Even if a prima facie case were established, Applicants have provided evidence of unexpected results sufficient to rebut a prima facie case of obviousness.

i. A prima facie case of obviousness has not been established.

To establish prima facie obviousness: 1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify or combine the teachings; 2) there must be a reasonable expectation of

success; and 3) the references must teach or suggest all of the claimed limitations. MPEP 2142. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Independent Claim 1 and Claims 2-7, 9-11, 13, 15 and 16 Depending Therefrom

Claim 1 is directed to a food composition for reducing blood cholesterol levels and controlling postprandial blood glucose and insulin levels which comprises a mixture of at least about 0.75 grams of beta-glucan soluble fiber or a source of beta-glucan soluble fiber per single reference serving and a non-digestible fat or a source of non-digestible fat.

The Office Action states that "it would have been obvious to one of ordinary skill in the art at the time the invention was made to employ beta glucan and polyol fatty acid esters in a food composition." This statement is made despite the candid admission that "Jandaceck, Akoh and FDA announcement abstract taken together, do not teach the combination of beta glucan and polyol fatty acid esters in a food composition and their particular amounts." The Office Action concludes that the combination is obvious because "one of skill in the art would have been motivated to employ beta glucan and polyol fatty acid esters in a food composition because they are both known to have antihypercholesteremic effects."

Applicants respectfully assert that the above reasoning is not sufficient to establish prima facie obviousness, neither with respect to claim 1, nor the claims depending therefrom.

First, there is no specific motivation or suggestion in Jandaceck to modify or combine its teachings, particularly, with what is disclosed in Akoh or the FDA announcement. Similarly, Akoh does not provide any specific motivation or suggestion to modify or combine its disclosure with what is taught in Jandaceck or the FDA announcement. The same applies to the FDA announcement. Applicants respectfully submit that the Examiner is improperly relying on hindsight in trying to establish a connection between all three references. Accordingly, Applicants respectfully submit that no suggestion or motivation exists in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify or combine the teachings of all three references.

Assuming *arguendo* that motivation exists to combine all three of these references, no reasoning whatsoever is provided with respect to the requirement for a reasonable expectation of

success. In particular, with respect to the presently pending claims, the Office Action must set forth reasoning to demonstrate that one of skill in the art would have a reasonable expectation of successfully combining at least about 0.75 grams beta glucan soluble fiber or a source of beta glucan soluble fiber per single reference serving, and a non-digestible fat or a source of non-digestible fat, in a traditional snack food. Applicants respectfully assert, for many of the reasons discussed below regarding the unexpected and surprising results achieved by the present invention, that no reasonable expectation of success for the combination can be shown. A successful combination of beta glucan soluble fiber and non-digestible fat in accordance with claim 1 requires that the formulation be a “traditional snack” food, while retaining sufficient fiber to be able to form the basis of a heart health claim under FDA guidelines, i.e., “at least 0.75 gram per single reference serving.” Prior to the present invention, it was not believed that these objectives were achievable. Kester Declaration at ¶ 4. In other words, for the reasons set forth in the Kester Declaration, one of ordinary skill in the art (at the time of the invention) would not have expected the combination of the cited references to successfully result in a traditional snack as defined by Applicants in the specification. “Traditional snack” is defined in the specification at page 3 as “baked goods ... salted snacks ... specialty snacks ... and confectionary snacks.” In summary, one of skill in the art would have expected the combination to result in a formulation contrary to Applicants’ definition of “traditional snack.” Kester Declaration at ¶ 4.

Moreover, the cited references do not teach or suggest all the claimed limitations. As discussed above, the Examiner concedes that “Jandaceck, Akoh and FDA announcement abstract taken together, do not teach the combination of beta glucan and polyol fatty acid esters in a food composition and their particular amounts.” There is no teaching regarding the amount of soluble fiber to incorporate into a traditional snack as claimed, i.e., 0.75 grams. About “0.75 gram” is the level required to meet the FDA standard for a heart health claim. This specific amount is not specifically taught or suggested anywhere in these references. Nevertheless, the Office Action states that “optimization of amounts is within the purview of the skilled artisan and is therefore obvious.” Applicants respectfully note, however, that deficiencies of references cannot be saved by appeals to “common sense” and “basic knowledge” without any evidentiary support. *In re Zurko*, 258 F.3d 1379 (Fed. Cir. 2001). But more importantly, the Kester Declaration provides objective evidence that in the case of snack foods, it was thought that the incorporation of the

claimed amount of beta glucan soluble fiber was not possible, much less “optimizable” with respect to the present invention. Kester Declaration, ¶ 4.

Claims 2-7, 9-11, 13, 15 and 16 depend from claim 1, and are therefore allowable. In addition, these claims are allowable because they contain additional patentable subject matter. Specifically, these claims require particular amounts of the recited elements, particular ratios of the recited elements and particular forms for the claimed snack food. None of these limitations are taught or suggested by the cited references. For the above reasons, it is respectfully asserted that each of claims 1, 2-7, 9-11, 13, 15 and 16 are allowable under 35 U.S.C. § 103 and Applicants request withdrawal of the rejection.

Independent Claim 23 and Claim 27 Depending Therefrom

Claim 23 requires “a sheetable dough comprising a sufficient amount of beta-glucan soluble fiber or source of beta-glucan soluble fiber to provide said dough with a beta-glucan soluble fiber level of at least 2% by weight.”

None of the cited references teach or suggest a “sheetable dough” having the claimed amount of soluble fiber, much less a dough having a soluble fiber level of at least 2%. As is the case with the amount of soluble fiber in claim 1, the percentage amount claimed for the sheetable dough of claim 23 corresponds to the amount required to make a heart health claim under FDA regulations. As discussed above with respect to claim 1 and the claims depending therefrom, and as discussed in the Kester Declaration as noted above, the claimed amount of fiber incorporated in a sheetable is not a matter of routine optimization.

Claim 27 depend from claim 23, and is therefore allowable. In addition, claim 23 is allowable because it contains additional patentable subject matter. Specifically, claim 27 requires a food made from the sheetable dough of claim 23. Because the sheetable dough itself is not taught or suggested, a food made from this dough is *a fortiori* not taught or suggested by the cited references, either.

Independent Claim 28

Claim 28 recites “a traditional snack food comprising, on a 30 gram basis, at least about 0.75 grams of beta-glucan soluble fiber.” This specific amount of fiber claimed for a traditional snack food, as discussed above, is not taught or suggested by the cited references. It is asserted,

therefore, that claim 28 is patentable over the cited references, and notification to that effect is earnestly solicited.

ii. Objective evidence demonstrates that the presently claimed invention is non-obvious.

For the reasons of record, Applicants maintain that the rejection does not establish a prima facie case of obviousness. Nevertheless, objective evidence of secondary considerations of non-obviousness is submitted herewith. Evidence of surprising and unexpected results can be sufficient to rebut a prima facie case of obviousness. MPEP 716.02(a). The Declaration of Dr. Jeffrey J. Kester (“Kester Declaration”) under 37 CFR 1.132 sets forth relevant evidence of unexpected results achieved by the presently claimed invention, and must therefore be considered. MPEP 716.01(a).

In the Declaration, Dr. Kester explains that the incorporation of beta glucan soluble fiber, in sufficient amounts to qualify under FDA guidelines for heart health claims, was thought to be especially problematic for traditional snack foods. Kester Declaration at ¶ 4. Moreover, “the difficulties in process and performance of these formulations are exacerbated even further when the traditional snack food contains a significant level of a non-digestible lipid, such as olestra.” Kester Declaration at ¶ 6. According to Dr. Kester, this is because “the whole-grain source of beta-glucan, such as oat bran or oat bran concentrate, must make up an even greater proportion of the non-lipid component of the traditional snack food.” Kester Declaration at ¶ 6.

Despite the problems known in the art to be associated with formulating a suitable traditional snack food composition using non-digestible fat and sufficient beta glucan soluble fiber, the Applicants successfully developed snack foods that accomplished these objectives and yet, remained tasty. The Kester Declaration sets forth objective evidence, in the form of sensory comparison data, which demonstrates that high fiber/olestra potato crisps were as palatable as control potato crisps. Kester Declaration at ¶ 10, “Sensory Test Results.”

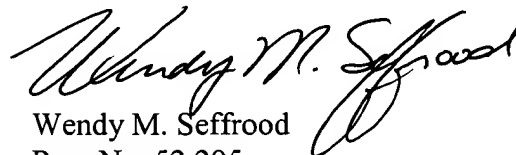
Dr. Kester concludes that “it was unexpected and contrary to prevailing assumptions that [the inventors] were able to develop formulations using both non-digestible fats and beta-glucan soluble fiber that were suitable for incorporation into a sheetable dough and that produced traditional snack foods that were surprisingly palatable.” Kester Declaration at ¶ 11.

In summary, the Kester Declaration provides ample evidence of unexpected and surprising results achieved by the presently claimed invention. Such evidence is sufficient to rebut a prima facie case of obviousness. MPEP 716.02(a). For these reasons, Applicants respectfully request withdrawal of the rejection under 35 U.S.C. § 103.

CONCLUSION

In view of the foregoing, reconsideration and allowance of claims is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone at the Examiner's convenience should any issues remain with respect to the Application.

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (AMENDED) A[n orally-administered] traditional snack food [composition of matter] for reducing blood cholesterol levels and controlling postprandial blood glucose and insulin levels in humans or lower animals, comprising a mixture of:

- (a) at least about 0.75 grams of beta-glucan soluble fiber or a source of beta-glucan soluble fiber per single reference serving; and
- (b) a non-digestible fat or a source of non-digestible fat.

5. (AMENDED) The composition of claim 1 wherein said composition is a food comprising, on a single reference serving basis:

- (a) at least about [0.5] 0.75 grams of beta-glucan soluble fiber; and
- (b) at least about 1 gram of non-digestible fat.

7. (AMENDED) The food of claim 5 wherein said food comprises:

- (a) from about [0.5] 0.75 grams to about 7.5 grams of beta-glucan soluble fiber; and
- (b) from about 1 gram to about 16.0 grams of non-digestible fat.

9. (AMENDED) The food of claim [8] 1 wherein said food is a cracker, filled cracker, potato crisp, extruded snack or filled extruded snack.

11. (AMENDED) The composition of claim 1 wherein said composition is a food comprising, on a 30 gram basis:

- (a) at least about [0.5] 0.75 grams of beta-glucan soluble fiber; and
- (b) at least about 1 gram of non-digestible fat.

13. (AMENDED) The food of claim 11 wherein said food comprises:

(a) from about [0.5] 0.75 grams to about 7.5 grams of beta-glucan soluble fiber; and

(b) from about 1 gram to about 16.0 grams of non-digestible fat.

15. (AMENDED) The food of claim [14] 11 wherein said food is a cracker, filled cracker, potato crisp, extruded snack or filled extruded snack.

23. (AMENDED) A sheetable dough comprising a sufficient amount of beta-glucan soluble fiber or source of beta-glucan soluble fiber to provide said dough with a beta-glucan soluble fiber level of at least about [1] 2% by weight.

28. (AMENDED) A traditional snack food comprising, on a 30 gram basis, at least about [0.5] 0.75 grams of beta-glucan soluble fiber.